

## T&L Biotechnology Ltd Product QC Report

Report number: 20220005

Name	Anti-Human CD137 Monoclonal Antibody	Catalog number	GMP-TL778-0100
Batch number	2208011	Specification	100μg/支(1mg/支)
Production Date	2022.08.30	Storage condition	2~8°C
Validity period	2024.08.29	Report date	2022.09.14

## Test items:

Project	Reference range	Result
Identify	Positive	Compliance
Physical behavior	Liquid	Compliance
Visible foreign matter	Should be no foreign bodies visible	Compliance
Deliverable volume	Not lower than the indicated value	Compliance
Mycoplasma	Negative	Compliance
Sterility test	Negative	Compliance
pH value	6.5~7.5	Compliance
Endotoxin	<0.01EU/μg	Compliance
Concentration	1.0 mg/ml~1.5mg/ml	Compliance
Purity	>95%	Compliance
Ioelectric point	The isoelectric point map of the test product was consistent with that of the control product	Compliance
Host cell DNA remains	The DNA residue in the samples was determined by Q-PCR to be less than 100pg/ml	Compliance
Host cell protein residues	The residue of host protein in the samples was determined by ELISA method to be less than 100ppm	Compliance
Conclusion	This product in accordance with the Chinese pharmacop enterprise internal standards test, the results meet	

Reported by: 2022.09.14